

REMARKS

Applicant requests reconsideration of the pending claims in this application in view of the foregoing amendments and the following remarks.

Status of Claims

Claims 73, 75, 80, 81, 90, 93-96, 99, 101, 105-109, 117-121 are currently pending, with claims 73, 75, 80, 81, 90, 93, 95, 101, 105, 106 and 108 being independent. Claims 1-72, 74, 76-79, 82-89, 91-92, 97-98, 100, 102-104 and 110-116 have previously been cancelled, without prejudice to or disclaimer of the subject matter recited therein. Claims 73, 75, 80, 81, 90, 101 and 105 are currently amended.

Applicant thanks the Examiner for allowing claim 93-96, 106-109, 119 and 120.

Obviousness Rejections

Claims 73, 75, 80, 81, 90, 99, 101, 105, 117, 118 and 121 have been rejected under 35 USC 103(a) as being unpatentable over U.S. Patent No. 5,731,319 to Aberg et al. in view of U.S. Patent No. 6,372,802 to Hellberg et al. Applicant traverses this rejection and requests that such rejections be withdrawn in view of the following remarks.

Applicant's claimed invention is patentable over both the Aberg et al. patent and the Hellberg et al. patent, taken together or separately.

Applicant respectfully disagrees with the assessments of patentability made in the Office Action as to various features included in the rejected claims. Nonetheless, in an effort to advance prosecution of this application, Applicant has amended each of claims 73, 75, 80, 81, 90, 101 and 105 to clarify that the desloratadine recited in those claims is in a free base form. Support for this amendment can be found, for example, in Structure I provided on Figure 1, which depicts desloratadine in a free base form. No new matter has been added.

The Office Action contends that Aberg et al. discloses compositions that include DCL (i.e., descarboethoxyloratadine) and antioxidants i.e. organic acids and cites col. 9, lines 12-30 of Aberg et al. This is not accurate. The Office Action changes the meaning of the passage in Aberg et al. by labeling the identified organic acids as antioxidants. For the Examiner's benefit, Applicant notes that col. 9, lines 12-30 reads as follows:

The term "pharmaceutically acceptable salt" refers to a salt prepared from pharmaceutically acceptable non-toxic acids or bases including inorganic acids or bases or organic acids or bases. Examples of such inorganic acids are hydrochloric, hydrobromic, hydroiodic, sulfuric, and phosphoric. Appropriate organic acids may be selected, for example, from aliphatic, aromatic, carboxylic and sulfonic classes of organic acids, examples of which are formic, acetic, propionic, succinic, glycolic, glucuronic, maleic, furoic, glutamic, benzoic, anthranilic, salicylic, phenylacetic, mandelic, embonic (pamoic), methanesulfonic, ethanesulfonic, pantothenic, benzenesulfonic, stearic, sulfanilic, algenic, and galacturonic. Examples of such inorganic bases include metallic salts made from aluminum, calcium, lithium, magnesium, potassium, sodium, and zinc. Appropriate organic bases may be selected, for example, from N,N-dibenzylethylenediamine, chlorprocaine, choline, diethanolamine, ethylenediamine, meglumaine (N-methylglucamine), lysine and procaine.

The term "antioxidant" is not mentioned in this passage. Rather, organic acids are mentioned in the context of preparing a pharmaceutical salt for DCL.

Each of the rejected claims (i.e., claims 73, 75, 80, 81, 90, 99, 101, 105, 117, 118 and 121) includes a solid composition containing desloratadine in a free base form and a desloratadine-protective amount of at least one pharmaceutically acceptable antioxidant. Applicant's claimed invention contemplates a composition in which the desloratadine remains in a free base form and does not create a "pharmaceutically acceptable salt" (as defined in the Aberg et al. patent). Accordingly, Applicant's invention cannot be considered to be obvious over the Aberg et al. patent. Therefore, Applicant respectfully requests withdrawal of the obviousness rejections.

Moreover, the Aberg et al. patent teaches away from what would be considered a "pharmaceutically acceptable antioxidant" as contemplated by Applicant's claimed invention by noting that carboxylic classes of organic acids and stearic acid are suitable organic acids that could be used to formulate a "pharmaceutically acceptable salt." However, as noted in Applicant's specification, organic acids such as stearic acid, hydroxycarboxylic acid and ascorbic acid cause discoloration and instability of desloratadine and so could not be considered "pharmaceutically acceptable antioxidants" (i.e., see para. [0028] of US 2004/0097536 A1). Thus, following the teachings of Aberg et al. would make the present invention inoperable. As such, Applicant submits that withdrawal of the rejection is appropriate.

The Hellberg et al. patent does not rectify the deficiencies in the teachings of the Aberg et al. patent. Consequently, the Aberg et al. patent, taken alone or in combination with the Hellberg

et al. patent, does not teach or render obvious Applicant's claimed invention.

In view of the above, Applicant submits that the remaining rejected claims are in condition for allowance in addition to those already identified in the Office Action as being allowed. Applicant further requests reconsideration and withdrawal of the outstanding rejections, as well as rapid passage of this application to issue. The Examiner is encouraged to contact Applicant's undersigned representative should there be any remaining issues precluding allowance of this application.

Dated: September 15, 2008
(September 13, 2008 = Saturday)

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